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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,051	10/19/2000	Ronald P. Lesser	P 268412 DM-3580	5363

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/691,051

Applicant(s)

LESSER ET AL.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear because in line 5 it appears "to at least" should be --to the at least--.

In claim 1, line 16 and claim 19, line 14 "such as" is indefinite.

Claim 6 is unclear because in line 4 it appears "by at least" should be --by the at least--.

Claim 23 is unclear because in lines 3-4 it appears "thereafter an active pulse is followed by recovery pulse" should be --thereafter the active pulse is followed by the recovery pulse--.

In claim 32, line 7, "optionally" is indefinite.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 3-11, 13-16, 19, 26-29, 31, 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Dorfmeister et al. (US 5995868). Dorfmeister et al. disclose a system that analyzes signals representative of a subject's brain activity using a processor (12) and intracranial electrodes (c 4, ll 64-66 and c 8, ll 37-48). The analysis of this brain activity enables warning, treatment and/or storage of the data to change or predict the change in state (c 5, ll 3-6 and c 9, ll 10-27). Additional sensors provide data on the patient's condition (c 9, ll 40-67 and c 13, ll 18-28). The outputs can be intracranial or extra cranial providing treatment to non-central nervous system organs (c 9, ll 10-15). An injector (32) is implanted for automated instantaneous release of the appropriate medicaments (c 9, ll 23-26). Signal processing includes adaptive analysis of waveform characteristics such as waveform analysis (c 5, ll 6-10 and c 16, ll 32-41).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2, 12, 20-25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of King et al. (US 5925070). As discussed in paragraph 3 of this action, Dorfmeister et al. discloses the claimed invention except for the charge balance of the current pulse sequence being ordered and maintained by dynamic feedback.

King et al. disclose controlling the locus of excitation of electrically excitable tissue and teach that it is known to provide tissue stimulation based on dynamic feedback to maintain charge balance (c 10, ll 43-65) to enable optimum tissue stimulation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that analyzes signals representative of a subject's brain activity as taught by Dorfmeister et al., with the pulse sequencing using charge balancing as taught by King et al. to provide optimum tissue stimulation by ensuring, with charge balancing, that the tissue is not damaged or destroyed by the imbalance in the charge field during the treatment periods.

6. Claims 17, 18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Ward et al. (US 5978702). As discussed in paragraph 3 of this action, Dorfmeister et al. disclose the claimed invention except for the medicament being a drug such as dopamine agonist.

Ward et al. disclose drug infusion techniques for treating epilepsy and teach that it is known to use a dopamine agonist to alter the neural environment of the brain (c 8, ll 37-43 and Table I.). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system that analyzes signals representative of a subject's brain activity as taught by Dorfmeister et al., with the inclusion in the medicament delivery system of a dopamine agonist as taught by Ward et al. to provide a specific drug that will alter the neural environment of the brain and alleviate the neural symptoms, specifically seizures.

***Other Prior Art Cited***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5314458 to Najafi et al. teaches charge balancing.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*9/26/02*

*[Signature]*  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER

*3762*  
*9/27/02*